obviousness-type double patenting as being unpatentable over Claims 1-10 of U.S. Patent 6,239,113.

Applicants submit herewith a Terminal Disclaimer, thereby rendering moot the Examiner's rejection.

On page 3 of the Office Action, the Examiner rejects Claims 47-48, 61-69, 83-84, 88-94 and 97-100 under 35 U.S.C. § 112, second paragraph.

Specifically, the Examiner states that in Claims 47-48 and 83-84, the term "comprises" is improper.

Applicants hereby amend Claims 47-48 and 83-84 to delete "comprises" and to substitute therefor "is".

Further, the Examiner contends that Claims 61-69 and 88-94 are substantially duplicates.

Applicants hereby cancel Claims 88-94, thereby rendering moot the Examiner's rejection.

In addition, the Examiner contends that Claims 97-98 and 99-100 are substantially duplicates.

Applicants hereby cancel Claims 99-100, thereby rendering moot the Examiner's rejection.

On page 4 of the Office Action, the Examiner rejects Claims 45-51, 71-72, 83-87 and 95-96 under 35 U.S.C. § 102(b) as being anticipated by Dawson.

Specifically, the Examiner states that Dawson discloses the claimed method of topically treating an eye infection with an azalide antibiotic.

For the following reasons, Applicants respectfully traverse the Examiner's rejection

Initially, Applicants note that, *inter alia*, dependent Claim 52 has not been included in this rejection. Hence, in

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view of the amendments to Claim 45 to include the recitation of Claim 52 therein, the Examiner's rejection has been rendered moot with respect to Claims 45-51 and 95-96.

As to Claims 71-72 and 83-87, these claims are directly or indirectly dependent on Claim 70. However, independent Claim 70 has not been included in this rejection. Thus, it is improper for the Examiner to reject Claims 71-72 and 83-87 over Dawson.

On page 5 of the Office Action, the Examiner rejects Claims 61-69, 88-94 and 97-102 under 35 U.S.C. § 103 as being unpatentable over WO 95/09601 or Curatolo et al.

Specifically, the Examiner states that WO 95/09601 (page 5 thereof) and Curatolo et al (column 8, lines 20-45 thereof) disclose suspensions of azithromycin and polymeric suspending agents, although not the specific amounts claimed. However, the Examiner contends that it would have been *prima facie* obvious to vary the amount of azithromycin and polymer to achieve the invention recited in these claims.

For the following reasons, Applicants respectfully traverse the Examiner's rejection.

Initially, as discussed above, the Examiner is requested to note that Applicants hereby cancel Claims 88-94 in view of the Examiner's previously objection that these claims are substantially duplicates of Claims 65-69. Similarly, Claims 99-100 are hereby cancelled.

As a result, only Claims 61-69, 97-98 and 101-102 remain included in this rejection.

Independent Claims 61, 65 and 101-102, as amended herein, relate to a topical ophthalmic composition.

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WO 95/09601 merely teaches a periodontal (buccal) composition. This composition can not be used in the eye, as such is not compatible in the eye.

Curatolo et al similarly relates to an oral composition, and thus does not teach or suggest the claimed topical ophthalmic composition.

Additionally, an ophthalmic composition preferably has a long shelf-like. One skilled in the art knows shelf-life is important for topical ophthalmic composition. Curatolo et al teaches that its oral composition has a shelf-life of only about 5 days (see column 8, lines 26-28 thereof).

Accordingly, Applicants respectfully submit that the present invention is not taught or suggested in WO 95/09601 or Curatolo et al, and thus request withdrawal of the Examiner's rejection

On page 5 of the Office Action, the Examine rejects Claims 65-66 and 88-89 under 35 U.S.C. § 102(b) as being anticipated by Bright.

Specifically, the Examiner states that Bright discloses a composition comprising azithromycin and an ophthalmically acceptable carrier, such as water (see column 7, lines 23-32).

For the following reasons, Applicants respectfully traverse the Examiner's rejection.

Initially, as discussed above, the Examiner is requested to note that Applicants have canceled Claims 88-89.

Further, Applicants note that, *inter alia*, Claim 67 has not been included in this rejection. Hence, in view of the amendment to Claim 65 to include the recitation of Claim 67 therein, the Examiner's rejection has been rendered moot.

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Finally, on page 5 of the Office Action, the Examiner rejects Claims 45-102 under 35 U.S.C. § 103 as being unpatentable over Davis et al in view of Bright.

Specifically, the Examiner states that Davis et al discloses ophthalmic suspensions for topical administration containing erythromycin. The Examiner notes that while Davis et al does not disclose a suspension containing azithromycin, since azithromycin is a derivative of erythromycin as disclosed by Bright, one skilled in the art would have been motivated to substitute azithromycin for erythromycin in the composition disclosed by Davis et al to achieve the present invention.

For the following reasons, Applicants respectfully traverse the Examiner's rejection.

Applicants respectfully submit that it would not have been obvious to substitute azithromycin for erythromycin to achieve the invention for the following reasons.

Azalides, e.g., azithromycin, contain a nitrogen in the ring. Erythromycin does not contain such a nitrogen. The presence of nitrogen in azalides results in the binding of the antibiotic to the cell tissue for long periods of time, which results in reduced ocular dosing. Further, azalides have enhanced stability in aqueous formulations.

On the other hand, erythromycin does not bind to cell tissue and an aqueous formulation of erythromycin can not be made because the drug is unstable. Ophthalmic products formulated as aqueous formulations must be stable for a minimum of 18 months to be commercially viable. Erythromycin in aqueous

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solution is only stable for less than one month, as compared to azithromycin which is stable for greater than 36 months.

Accordingly, Applicants respectfully submit that the present invention is not taught or suggested in Davis alone, and the combination with Bright can only be made in hindsight which is legally improper. Thus, Applicants request withdrawal of the Examiner's rejection.

In view of the amendments to the claims, and the arguments set forth above, reexamination, reconsideration and allowance are respectfully requested.

The Examiner is invited to contact the undersigned on any questions which might arise.

Respectfully submitted,

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